

REMARKS

In the non-final office action mailed January 13, 2006, claims 1-20, 50-58 and 91-105 were under consideration. Claims 1-7, 9-17, 19-20, 50-58, 91-100, and 105 were rejected. Claims 8, 18, and 101-104 were objected to as depending from a rejected base claim, but were indicated to be allowable if rewritten in independent form incorporating the base claim and any intervening claims. In this response, claims 21-49, 51 and 59-90 are cancelled, claims 1, 50, 53 and 91 are amended, and claims 106-134 are added. Reconsideration of the present application as amended and including claims 1-20, 50, 52-58 and 91-134 is respectfully requested.

Claims 1-7, 10, 12, 19, 50-55, 57, 58, 91-93, 96 and 105 were rejected under 35 USC §102(b) as being anticipated by DE 10027988 to Kosmala. A review of the translation of Kosmala provides a clear indication that Kosmala provides no disclosure, teaching or suggestion of the elements arranged as recited in several of the rejected claims. In particular, Kosmala discloses a first cannula, characterized in the office action as the second member, mounted to a first screw and a second cannula mounted to a second screw. The cannulae are connected by a bridge, which the office action characterizes as the first member. The bridge is located adjacent the proximal ends of the cannulae and is located outside the incision of the patient so that the intrusiveness of the procedure in the patient is minimized and to connect the proximal end of the cannulae to form a triangular shape. Only the cannulae extend into the patient. There is no disclosure that the bridge is axially movable relative to either of the cannulae, or that the bridge is movable along the axis of either of the cannulae to move the screw and the connecting element toward one another while the cannula is mounted to the screw.

Amended claim 1, in contrast, recites "an inserter engageable to a connecting element to percutaneously position the connecting element adjacent an anchor securable to at least one of the adjacent bony structures; and at least one anchor extension mountable to the anchor and extending along a longitudinal axis, wherein said anchor is manipulatable percutaneously with said at least one anchor extension to position said anchor for engagement with said connecting element, said at least one anchor extension including a first member and a second member, said second member being mountable to said anchor, and said first member and said second member

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being structured and configured to be axially movable relative to one another to contact said connecting element with said first member and move said anchor and said connecting element toward one another while said second member is mounted to said anchor.” Accordingly, Kosmala cannot disclose claim 1 and therefore withdrawal of this basis of the rejection is respectfully requested.

Claims 2-7, 10, 12 and 19 depending from claim 1 and rejected by Kosmala are allowable at least for the reasons claim 1 is allowable and for other reasons. For example, claim 4 recites “wherein said connecting element is moved in a direction transverse to said insertion axis with said first member of said at least one anchor extension as said connecting element and said anchor are moved toward one another.” Kosmala only discloses movement the connecting element along the insertion axis, and discusses in detail the importance of forming a triangle with the screw heads aligned along the insertion axis in order to be able to insert the connecting element between the screws. See paragraphs [0004] and [0008], for example, of the translation. Claim 5 recites “wherein during use said connecting element is engageable to said second anchor before said connecting element is moved toward said anchor with said first member of said at least one anchor extension.” Kosmala does not disclose any arrangement where the bridge can move the connecting element toward the anchor.

Claim 10 recites “wherein said first member is an outer sleeve with a passage and said second member is movably mounted in said passage of said first member.” A review of the drawings and translation of Kosmala finds no indication where the bridge includes any sleeve or any indication that the cannula is mounted in any passage of the bridge. The office action indicates that the bridge is a tube or a sleeve, but does not indicate where or how this is disclosed in Kosmala. Clarification for the basis of the rejection is respectfully requested if the rejection is maintained in the next office action. Claim 19 recites “wherein said connecting element includes a proximal portion, a distal portion, and a flexible intermediate portion therebetween.” The office action asserts that connecting element in Kosmala has a flexible portion, but does not indicate how or where this is disclosed. A review of the drawings and translation of Kosmala finds no indication of a connecting element with a flexible portion. Clarification for the basis of the rejection is respectfully requested if the rejection is maintained in the next office action. Accordingly,

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withdrawal of this basis of the rejection of claim 2-7, 10, 12 and 19 depending from claim 1 is respectfully requested.

Claim 50 has been amended and recites "an inserter engageable to a connecting element; and at least one anchor extension mountable with an anchor secured to a vertebra, wherein said inserter is movably mountable to said at least one anchor extension to move said connecting element along an insertion axis to a position adjacent said anchor, wherein said at least one anchor extension includes a first body and a second body coupled to said anchor, said first and second bodies forming a passage therebetween adapted to receive said connecting element therethrough along the insertion axis at a location spaced proximally from a proximal end of said anchor, wherein said anchor extension extends along a longitudinal axis and includes a first elongated sleeve and a second elongated sleeve, said first and second bodies being coupled to said second sleeve and said first sleeve extends about said second sleeve and is axially movable along said second sleeve with said first and second bodies located distally of said first sleeve and said passage being formed between said proximal end of said anchor and said first sleeve." Kosmala clearly fails to disclose or suggest any arrangement that includes an anchor extension with first and second elongated sleeves axially movable relative to one another and further fails to disclose other arrangements recited in claim 50. Accordingly, claim 50 is allowable and withdrawal of this basis of the rejection is respectfully requested.

Claims 52-55, 57 and 58 depending from claim 50 are allowable at least for the reasons claim 50 is allowable and for other reasons. For example, claim 53 recites "wherein said bodies are structured to form an enlarged passage portion therebetween along said passage that is enlarged relative to said passage at a location along said insertion axis." Kosmala fails to disclose any enlarged portion along the slot at the distal end of the cannula. Claim 54 recites "wherein said connecting element includes a proximal portion, a distal portion, and an enlarged intermediate portion extending therebetween." Kosmala does not disclose any connecting element with an enlarged intermediate portion, nor has the office action pointed out where such an enlarged intermediate portion is disclosed. Claim 55 depends from claim 54 and recites "wherein said enlarged passage portion is sized to receive said enlarged intermediate portion therethrough, and said proximal and distal portions are positionable in said passage between said proximal end of said

anchor and said enlarged passage portion.” Claim 55 is thus also not disclosed in Kosmala. Therefore, withdrawal of this basis of the rejection of claims 52-55, 57 and 58 depending from claim 50 is respectfully requested.

Claim 91 has been amended and recites “an inserter engageable to a connecting element; and at least one anchor extension extending along a longitudinal axis and mountable with an anchor secured to a vertebra, wherein said inserter is movably mountable to said at least one anchor extension to move said connecting element along an insertion axis to a position adjacent said anchor, wherein said at least one anchor extension includes a first member and a second member each extending along said longitudinal axis, said second member being mountable to said anchor and said first member and said second member being movable relative to one another along said longitudinal axis to contact said connecting element with said first member and move said anchor and said connecting element toward one another in a direction transverse to said insertion axis.” As discussed above with respect to claim 1, there is no disclosure in Kosmala that the bridge is axially movable to either of the cannulae, or that the bridge is movable along the axis of the cannula to move the screw and the connecting element toward one another while the cannula is mounted to the screw. Accordingly, Kosmala cannot anticipate claim 91 and withdrawal of this basis of the rejection thereof is respectfully requested.

Claims 92, 93 and 105 depending from claim 91 are allowable at least for the reasons claim 91 is allowable and for other reasons. For example, claim 105 recites “wherein said connecting element includes a proximal portion, a distal portion, and a flexible intermediate portion therebetween.” The office action does not provide any indication of where a connecting element with a flexible intermediate portion is disclosed in Kosmala, nor was any such disclosure located on review of its translation. If the rejection is maintained, clarification of the basis for the same in the next office action is respectfully requested. Withdrawal of this basis for rejecting claims 92, 93 and 105 depending from claim 91 is respectfully requested.

Claims 1-7, 9-17, 19, 20, 50-58, 91-100 and 105 were rejected under 35 USC §102(b) as being anticipated by PCT Publication No. WO 01/28436 to Sherman et al. Sherman discloses an inserter with anchor extensions mounted to anchors. The anchor extension includes an inner sleeve mounted to the anchor and an outer sleeve displaced distally along the inner sleeve to

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secure the distal arms of the inner sleeve to opposite sides of the anchor. The anchor extension is mounted to the anchors before mounting the inserter to the anchor extensions and before inserting the connecting element into the patient adjacent the anchor. The arrangement disclosed in Sherman includes the outer sleeve positioned adjacent the proximal end of the anchor to secure the inner sleeve to the anchor, and the connecting is guided into the anchor without moving the connecting element toward the anchor with the anchor extension since the outer sleeve does not move the connecting element and anchor toward one another when the inner sleeve is mounted to the anchor.

Amended claim 1, in contrast, recites "an inserter engageable to a connecting element to percutaneously position the connecting element adjacent an anchor securable to at least one of the adjacent bony structures; and at least one anchor extension mountable to the anchor and extending along a longitudinal axis, wherein said anchor is manipulatable percutaneously with said at least one anchor extension to position said anchor for engagement with said connecting element, said at least one anchor extension including a first member and a second member, said second member being mountable to said anchor, and said first member and said second member being structured and configured to be axially movable relative to one another to contact said connecting element with said first member and move said anchor and said connecting element toward one another while said second member is mounted to said anchor." Accordingly, Sherman cannot disclose claim 1 and therefore withdrawal of this basis of the rejection is respectfully requested.

Claims 2-7, 9-17, 19 and 20 depending from claim 1 and rejected by Sherman are allowable at least for the reasons claim 1 is allowable and for other reasons. For example, claim 4 recites "wherein said connecting element is moved in a direction transverse to said insertion axis with said first member of said at least one anchor extension as said connecting element and said anchor are moved toward one another." Sherman does not disclose moving the connecting element transversely to the insertion axis with the outer sleeve. Claim 5 recites "wherein during use said connecting element is engageable to said second anchor before said connecting element is moved toward said anchor with said first member of said at least one anchor extension."

Sherman does not disclose any arrangement where the outer sleeve moves the connecting element toward the anchor.

Claim 10 recites "wherein said first member includes a proximal housing portion, and further comprising a drive member rotatably received in said housing portion in engagement with said second member, said drive member being operable to move said first and second members relative to one another." A review of Sherman did not reveal a drive member arranged as recited in claim 10. If the rejection of claim 10 is maintained, then clarification of the basis for the rejection is respectfully requested. Claims 13-17 are directed to various features of the pivoting lock button, and it is not clear how Sherman could be considered to disclose the features recited therein particularly in view of the indication of the allowability of claims 101-104. Claim 19 recites "wherein said connecting element includes a proximal portion, a distal portion, and a flexible intermediate portion therebetween." The office action asserts that connecting element in Sherman has a flexible portion between proximal and distal portions, but does not indicate how or where this is disclosed. Clarification for the basis of the rejection is respectfully requested if the rejection is maintained in the next office action. Accordingly, withdrawal of this basis of the rejection of claim 2-7, 9-17, 19 and 20 depending from claim 1 is respectfully requested.

Claim 50 has been amended and recites "an inserter engageable to a connecting element; and at least one anchor extension mountable with an anchor secured to a vertebra, wherein said inserter is movably mountable to said at least one anchor extension to move said connecting element along an insertion axis to a position adjacent said anchor, wherein said at least one anchor extension includes a first body and a second body coupled to said anchor, said first and second bodies forming a passage therebetween adapted to receive said connecting element therethrough along the insertion axis at a location spaced proximally from a proximal end of said anchor, wherein said anchor extension extends along a longitudinal axis and includes a first elongated sleeve and a second elongated sleeve, said first and second bodies being coupled to said second sleeve and said first sleeve extends about said second sleeve and is axially movable along said second sleeve with said first and second bodies located distally of said first sleeve and said passage being formed between said proximal end of said anchor and said first sleeve." Sherman fails to disclose or suggest any arrangement that includes an anchor extension with a

passage formed between the proximal end of the anchor and the distal end of the outer sleeve. Rather, the proximal end of the anchor is located adjacent the distal end of the outer sleeve, and there is no passage between the proximal end of the anchor and the outer sleeve that receives the connecting element along the insertion axis. Accordingly, claim 50 is allowable and withdrawal of this basis of the rejection is respectfully requested.

Claims 52-58 depending from claim 50 are allowable at least for the reasons claim 50 is allowable and for other reasons. For example, claim 53 recites "wherein said bodies are structured to form an enlarged passage portion therebetween along said passage that is enlarged relative to said passage at a location along said insertion axis." A review of Sherman did not reveal an enlarged portion in the space 51 between arms 54 of the inner sleeve. If there is some other disclosure or basis in Sherman for believing such an arrangement is disclosed in Sherman, then clarification of the same is respectfully requested. Claim 54 recites "wherein said connecting element includes a proximal portion, a distal portion, and an enlarged intermediate portion extending therebetween." A review of Sherman did not reveal any connecting element with an enlarged intermediate portion, nor has the office action pointed out where such an enlarged intermediate portion is disclosed. If there is some disclosure or basis for believing that Sherman discloses such a connecting element, then clarification of the same is respectfully requested. Claim 55 depends from claim 54 and recites "wherein said enlarged passage portion is sized to receive said enlarged intermediate portion therethrough, and said proximal and distal portions are positionable in said passage between said proximal end of said anchor and said enlarged passage portion." Claim 55 is thus also not disclosed in Sherman. Claim 56 depends from claim 53 and further defines features of the enlarged passage portion not disclosed in Sherman. Therefore, withdrawal of this basis of the rejection of claims 52-58 depending from claim 50 is respectfully requested.

Claim 91 has been amended and recites "an inserter engageable to a connecting element; and at least one anchor extension extending along a longitudinal axis and mountable with an anchor secured to a vertebra, wherein said inserter is movably mountable to said at least one anchor extension to move said connecting element along an insertion axis to a position adjacent said anchor, wherein said at least one anchor extension includes a first member and a second

member each extending along said longitudinal axis, said second member being mountable to said anchor and said first member and said second member being movable relative to one another along said longitudinal axis to contact said connecting element with said first member and move said anchor and said connecting element toward one another in a direction transverse to said insertion axis." As discussed above with respect to claim 1, there is no disclosure in Sherman that the outer sleeve is axially movable relative to the inner sleeve to move the anchor and the connecting element toward one another while the inner sleeve is mounted to the screw. Rather, the outer sleeve is displaced distally along the inner sleeve to secure the anchor extension to the anchor before the connecting element is inserted. When the anchor extension is engaged to the anchor, the outer sleeve is adjacent to the proximal end of the anchor, and the connecting element is inserted into the anchor without moving or displacing the connecting element with the outer sleeve. Accordingly, Sherman cannot anticipate claim 91 and withdrawal of this basis of the rejection thereof is respectfully requested.

Claims 92-100 and 105 depending from claim 91 are allowable at least for the reasons claim 91 is allowable and for other reasons. For example, claim 97 recites "wherein said first member includes a proximal housing portion, and further comprising a drive member rotatably received in said housing portion in engagement with said second member, said drive member being operable to move said first and second members relative to one another." A review of Sherman did not reveal a drive member arranged as recited in claim 97. If the rejection of claim 97 is maintained, then clarification of the basis for the rejection is respectfully requested. In another example, claim 105 recites "wherein said connecting element includes a proximal portion, a distal portion, and a flexible intermediate portion therebetween." The office action does not provide any indication of where a connecting element with a flexible intermediate portion is disclosed in Sherman, nor was any such disclosure located on review of it. If the rejection is maintained, clarification of the basis for the same in the next office action is respectfully requested. Withdrawal of this basis for rejecting claims 92-100 and 105 depending from claim 91 is respectfully requested.

New claims 106-134 have been added in this response. Claim 106 is an independent claim directed to the subject matter of original claims 1 and 8. Claim 8 was indicated as being objected to in the Office Action Summary, and no reference was applied to reject it.

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Accordingly, new claim 106 is believed allowable along with claims 107- 124 depending therefrom. New claim 125 is an independent claim directed to the subject matter of original claim 101. Claims 126-134 depend from claim 125 and are also believed allowable.

In view of the foregoing, it is believed that claims 1-20, 50, 52-58 and 91-134 are in condition for allowance. Reconsideration of the present application as amended is respectfully requested. The Examiner is welcome to contact the undersigned to resolve any outstanding issues with regard to the present application.

Respectfully submitted,

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